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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/781,562 | 02/18/2004 | Zhong Zhao | GPT-032.01 | 9291 |

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| EXAMINER |
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FUBARA, BLESSING M

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| ART UNIT | PAPER NUMBER |
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1618

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04/02/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|---------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 10/781,562 | Applicant(s) ZHAO ET AL. | |
| | Examiner BLESSING M. FUBARA | Art Unit 1618 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-37, 39-47 and 50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-37, 39-47 and 50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The examiner acknowledges receipt of amendment and remarks filed 12/11/09. Claims 35-37 and 40-42 are amended. Claims 38 and 49 are canceled. New claim 50 is added. Claims 35-37, 39-47 and 50 are pending.

Response to Arguments

Previous rejections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 35-37, 39-41 and 43-47 and are rejected under 35 U.S.C. 102(b) as being anticipated by Barnette et al. (WO 02/04544).
4. Barnette discloses method of making polyphosphoester and polyphosphoester (claims 1, 6-10, 15-19, 22-27, 33, 35-38, 42, 43, 47 and 68); the polyphosphoester is biodegradable (page 4, lines 21-24) with the biodegradable term also meaning bioerodible (page 5, lines 16). Although claims 44 and 45 recite the properties of the composition, the disclosure of Barnette indicating biodegradability of the polyphosphoester further meets those claims. In certain embodiments, these polymers have associated therapeutic agents (page 5, lines 17-26) and are useful for in vivo

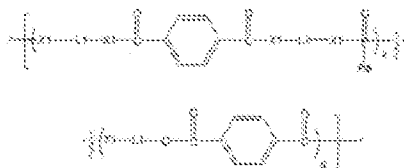
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therapy (page 4, lines 24-31) meeting claims 46 and 47. The polyphosphoesters comprise lactides and other groups containing aryl, cycloalkyl and alkyl groups (pages 7-9). In other embodiments the moieties attached to the phosphorus may be R6 or R8 and these moieties are aralalkyl, aryl, O-aryl (page 7, page 8 at lines 19, 24-27).

Response to Arguments

5. Applicant's arguments filed 12/11/09 have been fully considered but they are not persuasive.

6. Applicant argues that the polyphosphoesters of Barnette does not have lactide and reproduced the structure and data below from page 20 and 21 of Barnette:

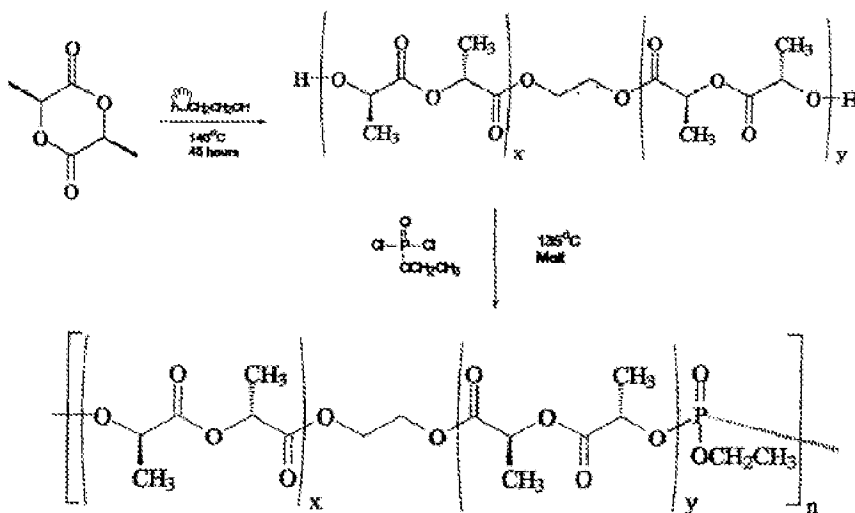


Structure V

| Abbreviation | ARX1 | AR13 | R8 |
|--------------|------|---|-----------------------------------|
| PBHP1-PBP13 | Q | CH ₂ CH ₂ | -OCH ₂ CH ₂ |
| PBHP1-PBP13 | Q | CH ₂ CH ₂ CH ₂ CH ₂ | -OCH ₂ CH ₂ |
| PBHP1-PBP13 | Q | CH ₂ CH ₂ CH ₂ CH ₂ | -OCH ₂ CH ₂ |
| PBHP1-PBP13 | Q | CH ₂ CH ₂ CH ₂ | -OCH ₂ CH ₂ |
| PBHP1-PBP13 | Q | CH ₂ CH ₂ CH ₂ CH ₂ | -OCH ₂ CH ₂ |

7. But applicant is referring to one embodiment. There are other embodiments that have the lactide in the phosphoester compound. For example, page 2 of Barnette shows the reaction of the opened lactide with ethyl phosphodichloridate to form poly(L-lactide-co-ethyl phosphate)

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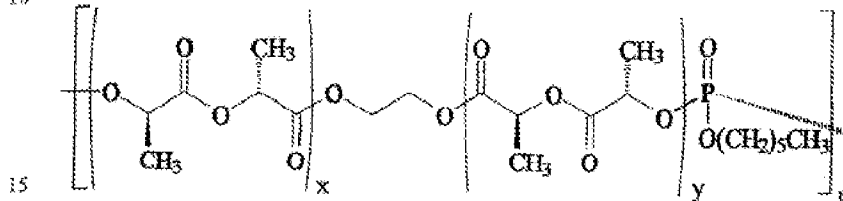


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This example is Poly(L-lactide-co-ethyl phosphate), referred to as Poly(LAEG-EOP).

Similar approaches have been used to form Poly(L-lactide-co-hexyl phosphate), referred to as Poly(LAEG-HOP), except that hexyl phosphodichloridate (HOP) substitutes for ethyl phosphorodichloridate (EOP). The polymer is depicted below:

10



15

1.

-2-

Furthermore, Formula I, II, IIIa and IIIb, IIIc, IIId, IIIe and IIIf tell the story.

These structures are the structures in the examined claimed case.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 35-37, 39-47 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barnette et al. (WO 02/04544).

11. Barnette is described above. The moiety attached to the P is the chemical moiety. The simplest is represented above as –OR. But other groups such as R6 and R8 may also be the chemical moiety L2. Various chemical moieties are disclosed in the publication such as the aryl, aryloxy, aralkyloxy, O-aryl and other suitable aromatic (page 8, lines 24-27). However, Barnette does not specifically teach the chemical moieties of claims 38, 42 and 49. But the aryl chemical moieties are homologous to the –C(O) C₆H₄C(O)-groups so that one can be used in place of the other.

Response to Arguments

12. Applicant's arguments filed 2/17/09 have been fully considered but they are not persuasive.

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13. Applicant argues that L2 in the claims and in particular claims 38 and 49 is $-\text{C}(\text{O})\text{C}_6\text{H}_4\text{C}(\text{O})-$. The examiner agrees that in claims 38 and 42, the L2 is required to be $-\text{C}(\text{O})\text{C}_6\text{H}_4\text{C}(\text{O})-$, but in claim 35, the $-\text{OCH}_2\text{CH}_2\text{O}-$ moiety meets the broad limitation of $-\text{C}(\text{O})-$. Thus Barnette teaches the limitations of claims 35 and renders obvious the L2 Moiety of claims 38 and 42.

Response to Arguments

14. Applicant's arguments filed 12/11/09 have been fully considered but they are not persuasive.

15. Applicant argues that Barnette does not teach all the limitations of the claims as applicant discussed in the prior presentation.

16. The examiner disagrees because the examiner has shown that applicant is relying on one embodiment while the other embodiments teach, for example, polyphosphoesters that comprise lactides and other groups containing aryl, cycloalkyl and alkyl groups (pages 7-9), and also poly(L-lactide-co-ethyl phosphate). The question in consideration of obviousness is whether the invention would have been obvious in light of the reference(s). In the present case, aryl chemical moieties are homologous to the $-\text{C}(\text{O})\text{C}_6\text{H}_4\text{C}(\text{O})-$ groups so that one can be used in place of the other and the claims shall have been rendered obvious.

17. No claim is allowed.

18. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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19. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on Monday to Thursday from 7 a.m. to 5:30 p.m.

21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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22. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Primary Examiner, Art Unit 1618